

JCG:DBS

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,	)	CASE NO.:
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
PETER J. BADDICK, III., DO.	)	
	)	
Defendant.	)	

**COMPLAINT**

Plaintiff, the United States of America, by its attorney, John C. Gurganus, United States Attorney for the Middle District of Pennsylvania, alleges as follows:

**I. INTRODUCTION**

1. This is a civil fraud action brought by the United States against Dr. Peter J. Baddick, III, under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, to recover treble damages and civil penalties and for damages under the common law theory of payment by mistake of fact resulting from false and/or fraudulent claims for controlled substance prescriptions that Dr. Baddick caused to be submitted to the Medicare Program and TRICARE.

## **II. JURISDICTION AND VENUE**

2. The United States brings this action pursuant to the False Claims Act (FCA), 31 U.S.C. §3729, *et seq.*

3. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § § 1331 and 1345.

4. The Court may exercise personal jurisdiction over the defendant pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the defendant can be found in and has transacted business within the Middle District of Pennsylvania.

5. Venue is proper in the Middle District of Pennsylvania under 31 U.S.C. § 3732(a), because Dr. Baddick's actions caused a pharmacy located in the Middle District of Pennsylvania to submit false claims to the Medicare Program and TRICARE in violation of 31 U.S.C. § 3729.

## **III. THE PARTIES**

6. Plaintiff is the United States of America.

7. Defendant Dr. Peter J. Baddick, III, is an individual residing in the Commonwealth of Pennsylvania.

8. In 1994, Dr. Baddick received a medical degree from the Philadelphia College of Osteopathic Medicine.

9. In 1995, Dr. Baddick received an Osteopathic Physician and Surgeon license (No. OS008960L) from the Commonwealth of Pennsylvania.

10. Dr. Baddick does not hold any board certifications.

11. In 1996, Dr. Baddick applied for and received DEA authorization to prescribe Schedule II, III, IV and V controlled substances.

12. At times relevant to this Complaint, Dr. Baddick has practiced family medicine within the Middle District of Pennsylvania.

#### **IV. LEGAL AND REGULATORY FRAMEWORK**

##### **A. THE CONTROLLED SUBSTANCES ACT**

13. The Controlled Substances Act (CSA) governs the manufacture, distribution, and dispensation of controlled substances in the United States. In order to prevent any person from diverting controlled substances from legitimate to illegitimate uses, the CSA established a closed regulatory system under which it is unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.

14. The CSA classifies controlled substances into five schedules: I, II, III, IV and V. 21 U.S.C. § 812(c); 21 C.F.R. § 1308.01.

15. Schedule II controlled substances are drugs that have an accepted medical use but have a high potential for abuse which may lead to severe psychological or physical dependence. 21 U.S.C. § 812(b)(2).

16. The CSA classified Subsys as a Schedule II drug.

**B. THE FALSE CLAIMS ACT**

17. The False Claims Act (FCA) provides, in pertinent part, that any person who:

- (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- (B) knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent; [or]
- (C) conspires to commit a violation of subparagraph (A) [or] (B) . . .
- (D) is liable to the United States Government [for statutory damages and such penalties as are allowed by law]. 31U.S.C. §§ 3729(a)(1)-(3) (2006), as amended by 31 U.S.C. § 3729(a)(1)(A)-(C) (2010).

18. The FCA further provides that “knowing” and “knowingly”

- (A) means that a person, with respect to information —
  - i. has actual knowledge of the information;
  - ii. acts in deliberate ignorance of the truth or falsity of the information; or

iii. acts in reckless disregard of the truth or falsity of the information; and

(B) requires no specific intent to defraud.

31 U.S.C. § 3729(b) (2006), as amended by 31 U.S.C. § 3729(b)(1) (2010).

19. The FCA, 31 U.S.C. § 3729(a)(1), provides that any person who violates the FCA is liable to the United States Government for three times the amount of damages which the Government sustains because of the act of that person, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of the FCA 31 U.S.C. § 3729 and 28 C.F.R. § 85.3(a)(9).

### **C. THE MEDICARE PROGRAM**

20. Congress established the Medicare Program in 1965 to provide health insurance coverage for people age 65 or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 1395, et. seq.

21. Medicare is funded by the federal government and administered by the Centers for Medicare & Medicaid Services (CMS), which is part of the United States Department of Health and Human Services (HHS).

22. The Medicare program consists of four parts: A, B, C, and D. Defendant here submitted, or caused to be submitted, claims under Medicare Parts B and D.

23. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription drug benefit program for Medicare enrollees known as Medicare Part D.

24. Part D coverage is not provided within the traditional Medicare program. Medicare Part D is based on a private market model. Medicare contracts with private entities known as Part D Plan “Sponsors” to administer prescription drug plans.

25. Part D benefits are delivered by a Part D Plan Sponsor, which is either a prescription drug plan, a Medicare Advantage organization that offers a Medicare Advantage prescription drug plan (MA-PD plan), a Program of All-inclusive Care for the Elderly (PACE) organization offering a PACE plan including qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage. 42 C.F.R. § 423.4.

26. When a pharmacy dispenses a drug to a Medicare beneficiary,

it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the Part D Plan Sponsor for the costs not paid by the beneficiary.

27. The Part D Plan Sponsor then notifies CMS that a drug has been dispensed to a Medicare Part D beneficiary through a data file called a Prescription Drug Event (PDE) record, which includes data elements about the drug dispensed, the prescription, and the payment to the pharmacy.

28. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies. The data contained in PDEs are data related to payment of claims. The Integrated Data Repository (IDR) process date is the date when the PDE is transmitted to CMS, such that CMS is informed of the PDE by the Part D Plan Sponsor.

29. In addition, CMS uses the information in the PDE at the end of the payment year to reconcile its advance payments to the sponsor with actual costs the plan sponsor incurred. See "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)" (April 27, 2006).

30. Throughout the year, CMS makes prospective payments to Part D Plan Sponsors for three subsidies based on the Sponsors' approved bids: (1) the direct subsidy designed to cover the Sponsor's cost of providing the benefits; (2) the low-income cost-sharing subsidy; and (3) the reinsurance subsidy.

31. The direct subsidy (a monthly capitated payment) is paid to the Part D Plan Sponsor in the form of advance monthly payments equal to the Part D Plan's standardized bid, risk adjusted for health status as provided in 42 C.F.R. § 423.329(b), minus a monthly beneficiary premium as determined in 42 C.F.R. § 423.315(b). In other words, CMS pays a monthly sum to the Part D Plan Sponsor for each Part D beneficiary enrolled in the plan.

32. CMS also makes payments to the Part D Plan Sponsor for premium and cost sharing subsidies on behalf of certain subsidy-eligible individuals as provided in 42 C.F.R. § 423.780 and 42 C.F.R. § 423.782. Cost-sharing subsidies for qualifying low-income individuals are called "Low-Income Cost Sharing Subsidies (LICS)" and are documented and reconciled using PDE data submitted to CMS.

33. Part D sponsors who fail to submit required claims-level



information contained in the PDE to CMS risk having to return the monthly payments to CMS during reconciliation. *See* 42 C.F.R. § 423.343(b), (c)(2) and (d)(2). In addition, Part D Sponsors are responsible for correcting submitted PDE data they determine are erroneous. *See* “Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)” at 4 (April 27, 2006).

34. After the close of the plan year, CMS is responsible for reconciling the prospective payments to the Part D Sponsor’s actual allowable costs by relying upon data elements submitted by Sponsors in their PDE records and direct and indirect remuneration (IDR) data.

35. In order to receive Part D funds from CMS, Part D Plan Sponsors, their authorized agents, employees, and contractors are required to comply with all applicable federal laws, regulations, as well as CMS instructions.

36. By statute, all contracts between a Part D Plan Sponsor and HHS must include a provision whereby the Plan Sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112.

37. Medicare Part D Plan Sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 505(h)(1).

38. CMS regulations require that all subcontracts between Part D Plan Sponsors and downstream entities contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions, including the CSA. 42 C.F.R. § 423.505(i)(4)(iv).

39. A Part D Plan Sponsor is required by federal regulation to certify to the accuracy, completeness and truthfulness of all data related to the payment. This provision, entitled “Certification of data that determine payments,” provides in relevant part, as follows:

(1) General Rule. ***As a condition for receiving a monthly payment . . . the Part D Plan sponsor agrees that*** its chief executive officer (CEO) chief financial officer (CFO), or ***an individual*** delegated the authority to sign on behalf of one of these officers, . . . ***must request payment under the contract on a document that certifies*** (based on best knowledge, information and belief) the ***accuracy, completeness, and truthfulness*** of all data related to payment.

. . .

(2) [Part D Sponsor] Certification of Claims Data: The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, . . . must certify (based on best knowledge, information and belief) that the claims data it submits . . . are accurate, complete and truthful and

acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k)(1), (k)(3) and (k)(5) (emphasis added).

40. All approved Part D Plan Sponsors who received payment under Medicare Part D in benefit years relevant to this case submitted the required attestations for data submitted that related to payment. 42 C.F.R. § 423.505(k).

41. The “Certification of data that determines payments” provision of the applicable regulation further provides: “[i]f the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement.” 42 C.F.R. § 423.505(k)(3).

42. Compliance with the requirement that PDE data submitted by the Plan Sponsor is “true, accurate, and complete” is a condition of payment to the Plan Sponsor under the Medicare Part D Program. *Id.* and 42 C.F.R. § 423.505(k)(5).

43. Medicare only covers drugs that are used for a medically

accepted indication, which means a use that is approved under the Food, Drug, and Cosmetic Act, or a use which is supported by one or more citations included or approved for inclusion in one of the specified compendia. 42 U.S.C. § 1395w-102(e)(1) & (e)(4); 42 U.S.C. § 1396r-8(g)(1)(B)(i) & (k)(6); 42 C.F.R. § 423.100.

44. PDEs submitted to Medicare for drugs that are not for a medically accepted indication do not contain accurate, complete and truthful information about all data related to payment.

45. Medicare only covers drugs that are dispensed upon a prescription. 42 U.S.C. § 1395w-102(e); 42 C.F.R. § 423.100. A “Part D sponsor may only provide benefits for Part D drugs that require a prescription if those drugs are dispensed upon a valid prescription.” 42 C.F.R. § 423.104(h). A valid prescription must comply “with all applicable State law requirements constituting a valid prescription.” 42 C.F.R. § 423.100.

46. Part D plans may also exclude drugs from payment if the drugs are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve functioning of a malformed body part.

42 U.S.C. § 1395w-102(e)(3) (incorporating by reference 42 U.S.C. § 1395y(a)).

47. Prescriptions for controlled substances that are not issued for a legitimate medical purpose are not for “medically accepted indications” and are therefore not covered Medicare Part D drugs. 42 U.S.C. § 1395w-102(e)(1).

48. Prescriptions for controlled substances that are not issued for a legitimate medical purpose are not “valid prescriptions” under Pennsylvania law, 28 Pa. Code § 25.51 and § 25.52, and are therefore not covered Medicare Part D drugs. 42 U.S.C. § 423.104(h).

49. PDEs submitted to Medicare for controlled substances that are dispensed when not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice do not contain accurate, complete and truthful information about all data related to payment.

#### **D. THE TRICARE PROGRAM**

50. TRICARE is a federal healthcare program that is administered by the Defense Health Agency (DHA), a component of the Department of Defense (DoD). TRICARE provides health care insurance for active-duty military personnel, military retirees, and military

dependents. The funds used by TRICARE to pay medical claims of qualified individuals are appropriated funds. 32 C.F.R.

§ 199.1(e).

51. TRICARE offers its beneficiaries a prescription drug benefit. TRICARE beneficiaries may receive prescription drugs from three different sources: military treatment facilities, the TRICARE Mail Order Pharmacy, and retail pharmacies.

52. TRICARE will only pay “for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care. . . . However, TRICARE benefits cannot be authorized to support or maintain an existing or potential drug abuse situation whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means.” 32 C.F.R. § 199.4.

53. When a TRICARE beneficiary’s prescription is submitted to a TRICARE network pharmacy, the pharmacy submits an electronic claim to the Pharmacy Benefit Manager (PBM) for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary’s TRICARE coverage, and if the prescription

claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a ten-day hold to ensure the prescription medication is delivered to the patient (and not returned to the shelf by the pharmacy), the PBM sends a TRICARE Encounter Data (TED) record electronically to TRICARE. The TED record includes information regarding the prescription event, including the prescriber's identity, the date the prescription was written, the number of refills authorized, the number of times the prescription has been filled, the amount claimed for reimbursement, and information on drug coverage under TRICARE.

54. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank (FRB). The FRB then transfers funds to the PBM's bank account.

55. All pharmacies that provide services to TRICARE beneficiaries are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. § 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Billing for costs for non-covered services is included within the definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b), 199.9(c)(2). More specifically, under TRICARE regulations, “[m]isrepresentations of dates, frequency, duration, or description of services rendered, or of the identity of the recipient of the services or the individual who rendered the services” are “presumed to be fraud.” *Id.* § 199.2(c)(6).

56. Prescriptions for controlled substances that are not for medically accepted indications are not covered by TRICARE.

57. During the relevant time period, Dr. Baddick wrote prescriptions for Subsys for a TRICARE beneficiary that were not for medically accepted indications. These prescriptions were filled by a pharmacy.

58. Because it is not feasible for the TRICARE program, or its contractors, to review medical records corresponding to each of the claims



for payment it receives from providers, the program relies on providers to comply with TRICARE requirements and relies upon providers to submit truthful and accurate certifications and claims.

## **V. FACTS**

### **A. INSYS THERAPEUTICS AND SUBSYS**

59. Insys was a pharmaceutical company that developed and commercialized Subsys, a sublingual fentanyl spray. Subsys is classified as a transmucosal immediate-release fentanyl.

60. Subsys was approved by the U.S. Food and Drug Administration in 2012 to treat breakthrough pain in adult cancer patients who are opioid tolerant.

61. Insys developed a “speaker program” where Insys would recruit and pay prescribers of Subsys to give presentations on the drug during peer-to-peer lunches and dinners.

62. Dr. Baddick attended multiple Insys speaker program events in Pennsylvania.

63. In order to prescribe Subsys, medical providers were required to enroll in the FDA’s Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access Program. A

copy of a TIRF REMS ACCESS Prescriber Enrollment Form is attached as Exhibit A.

64. To be enrolled in the TIRF REMS Access Program a provider was required to certify that she/he “reviewed the TIRF REMS Access Education Program, including Full Prescribing Information for each TIRF medicine, and I have completed the Knowledge Assessment.” Ex. A.

65. To be enrolled in the TIRF REMS Access Program a provider was required to certify that she/he understood “that TIRF medicines are indicated only for the management of breakthrough pain in patients with cancer . . .” Ex. A.

66. At times relevant to this Complaint, Dr. Baddick was enrolled in the TIRF REMS Access Program.

67. Dr. Baddick was aware that Subsys was only approved by the FDA to treat breakthrough cancer pain in adults who were opioid-tolerant.

68. In 2015, Dr. Baddick began to prescribe Subsys to his non-cancer patients.

**B. DR. BADDICK'S PRESCRIPTION PRACTICES**

69. At times relevant to this Complaint, Dr. Baddick saw patients at his medical practice, Penn Medical Group, P.C., located at 2175 Blakeslee Boulevard, Lehighton, PA 18235. Dr. Baddick was the sole shareholder of the Penn Medical Group beginning in 1999.

70. Penn Medical Group, P.C. ceased operations on or about September 28, 2019.

71. As a DEA registered physician, Dr. Baddick had a legal responsibility to prescribe Schedule II drugs, including Subsys, in accordance with the CSA.

72. At times relevant to this Complaint, Dr. Baddick would post-date Subsys prescriptions for future dates.

73. At times relevant to this Complaint, Dr. Baddick repeatedly prescribed Subsys, a Schedule II drug, under circumstances that were not for a legitimate medical purpose in the usual course of professional practice under Pennsylvania law. These patients include the following:

**PATIENT M.G.**

74. At all times relevant to this Complaint, Patient M.G. was a Medicare beneficiary.

75. Dr. Baddick had been treating M.G. since at least 2006.

76. Medical records maintained by Dr. Baddick indicate that he saw M.G. on April 1, 2015 for back pain. M.G. complained of back pain for 25 years and stated she had received 23 injections to manage her pain. The progress notes reflect that during the time M.G. was seen by Dr. Baddick she had been diagnosed with chronic pain, herniated nucleus pulposus lumbar and gastroesophageal reflux disease among other maladies. There is no indication that M.G. was ever diagnosed with cancer.

77. On April 2, 2015, Dr. Baddick signed an INSYS Reimbursement Center and Patient Authorization & Referral Form indicating that M.G. had been diagnosed with degeneration of cervical intervertebral disc/degeneration of cervicothoracic intervertebral disc, chronic pain and chronic pain syndrome.

78. On April 1, 2015, Dr. Baddick prescribed Subsys 200 mcg 4 times a day (30 units) to M.G.

79. M.G.'s April 1, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy \$1,280.94 for the April 1<sup>st</sup> Subsys prescription written by Dr. Baddick.

80. Dr. Baddick's medical records indicate that he saw M.G. on April 20, 2015, to follow up on back pain. The progress notes indicate that M.G. was diagnosed with chronic pain syndrome.

81. The progress notes reflect that on April 20, 2015, Dr. Baddick prescribed Subsys 1200 mcg 4 times a day (180 units) to M.G. Dr. Baddick provided a prescription written to M.G. for Subsys 1200mcg dated April 17, 2015.

82. M.G.'s April 17, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy \$15,202.14 for the April 17<sup>th</sup> Subsys prescription written by Dr. Baddick.

83. An April 23, 2015, progress note indicates that M.G. called Dr. Baddick's office to express concern that she may be having a reaction to Subsys. M.G. reported that her heart rate was increased on April 22, 2015, and M.G. called an ambulance to her home. M.G. stated that she was evaluated by the ambulance crew and was determined to be fine.

84. On or about May 12, 2015, a pharmacy submitted a claim to Medicare Part D for a prescription of Subsys 1200 mcg (180 units) written by Dr. Baddick. Medicare paid the pharmacy \$15,146.14. for the

aforementioned Subsys prescription. Dr. Baddick has not provided any medical records that appear to correspond to the aforementioned Subsys prescription.

85. Dr. Baddick's medical records indicate that he saw M.G. on May 18, 2015, for a monthly medication check and refills on prescriptions for OxyContin and Ambien. The medical notes reflect that M.G. told Dr. Baddick Subsys was working fine. The medical records do not indicate that Dr. Baddick wrote a Subsys prescription for M.G. during this visit.

86. On or about June 2, 2015, a pharmacy submitted a claim to Medicare Part D for a prescription of Subsys 1200 mcg (240 units) written by Dr. Baddick. Medicare paid the pharmacy \$20,194.60 for the aforementioned Subsys prescription. Dr. Baddick has not provided any medical records that appear to correspond to the aforementioned Subsys prescription. Dr. Baddick provided a prescription written to M.G. for Subsys 1200 mcg dated June 1, 2015.

87. Dr. Baddick's medical records indicate that he saw M.G. on June 24, 2015, for a monthly medication check and refills on prescriptions for OxyContin and Subsys. The medical notes again reflect that M.G. was being treated for chronic pain syndrome and back pain.

88. On June 24, 2015, Dr. Baddick prescribed Subsys 1200 mcg 4 times a day (240 units) to M.G.

89. M.G.'s June 24, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy \$20,194.60 for the June 24<sup>th</sup> Subsys prescription written by Dr. Baddick.

90. Dr. Baddick's medical records indicate that he saw M.G. on July 22, 2015, for a monthly medication check and prescription refill on Ambien. Progress notes reflect that M.G. stated that a Subsys prescription would need to be called into the pharmacy on July 24, 2015. The medical notes again reflect that M.G. was being treated for chronic pain syndrome and back pain.

91. On July 22, 2015, Dr. Baddick prescribed Subsys 1200 mcg 4 times a day (240 units) to M.G.

92. M.G.'s July 22, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy \$23,161.25 for the July 22<sup>nd</sup> Subsys prescription written by Dr. Baddick.

93. Dr. Baddick's medical records indicate that he saw M.G. on August 19, 2015, for a monthly medication check and prescription refills for Subsys, Ambien and OxyContin. The medical notes again reflect that M.G. was being treated for chronic pain syndrome and back pain.

94. On August 19, 2015, Dr. Baddick prescribed Subsys 1200 mcg 4 times a day (240 units) to M.G.

95. M.G.'s August 19, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy \$23,161.25 for the August 19<sup>th</sup> Subsys prescription written by Dr. Baddick.

96. Medical records maintained by Dr. Baddick include a progress note dated September 14, 2015, stating that M.G.'s prescription refill for Subsys 1200 mcg (240 units) is scheduled for September 16, 2015.

97. Dr. Baddick's medical records indicate that he saw M.G. on September 16, 2015, for a monthly medication check and a prescription refill for Oxycontin.

98. On September 16, 2015, Dr. Baddick prescribed Subsys 1200 mcg 4 times a day (240 units) to M.G.



99. M.G.'s September 16, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy \$23,161.25 for the September 16<sup>th</sup> Subsys prescription written by Dr. Baddick.

100. Dr. Baddick's medical records indicate that he saw M.G. on October 12, 2015, for a monthly medication check and a prescription refill for OxyContin. The medical notes again reflect that M.G. was being treated for chronic pain syndrome and back pain.

101. On October 12, 2015, Dr. Baddick prescribed Subsys 1200 mcg 4 times a day (240 units) to M.G.

102. M.G.'s October 12, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy \$23,161.25 for the October 12<sup>th</sup> Subsys prescription written by Dr. Baddick.

103. Dr. Baddick's medical records indicate that he saw M.G. on November 2, 2015, for a monthly medication check and prescription refills for OxyContin, Ambien and Subsys. The medical notes again reflect that M.G. was being treated for chronic pain.

104. On November 2, 2015, Dr. Baddick prescribed Subsys 1200 mcg four times a day (240 units) to M.G.

105. M.G.'s November 2, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy \$23,161.25 for the November 2<sup>nd</sup> Subsys prescription written by Dr. Baddick.

106. Dr. Baddick's medical records indicate that he saw M.G. on December 1, 2015, for a monthly medication check and prescription refills for OxyContin and Subsys. The medical notes again reflect that M.G. was being treated for chronic pain and back pain.

107. On December 1, 2015, Dr. Baddick prescribed Subsys 1200 mcg (240 units) to M.G.

108. M.G.'s December 1, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to Medicare Part D. Medicare Part D paid the pharmacy \$23,161.25 for the December 1<sup>st</sup> Subsys prescription written by Dr. Baddick.

109. Dr. Baddick's medical records indicate that he saw M.G. on December 22, 2015, and that M.G. was being seen for Subsys withdrawal. The progress notes reflect that M.G. had been out of Subsys since

December 18, 2015. M.G. admitted using more Subsys in December than usual. M.G. requested to discuss other pain management strategies and states she did not want to take medications with withdrawal reactions.

110. The progress notes of December 22, 2015, reflect that M.G. was complaining of shortness of breath, chest pain, hot and cold flashes, and felt like bugs were crawling on her skin.

111. The December 22, 2015, progress note assessment and plan states that Dr. Baddick's impression was that M.G. was experiencing opioid withdrawal and polysubstance abuse.

112. The December 22, 2015, progress note stated that M.G. would discontinue Subsys as of December 22, 2015.

113. Dr. Baddick's medical records indicate that he saw M.G. on December 29, 2015, and that M.G. was being seen to follow up on Subsys withdrawal. The progress notes reflect that M.G. reported feeling better and did not want to take Subsys.

114. The December 29, 2015, progress note assessment and plan states that Dr. Baddick's impression was that M.G. was feeling better after discontinuing Subsys and was no longer experiencing withdrawal symptoms.

115. All of Dr. Baddick's prescriptions for Subsys to Patient M.G. from April of 2015 through December of 2015 are identified below:

<b>Date of Rx</b>	<b>Details/Dosage</b>	<b>Paid by Medicare</b>
4/1/2015	Subsys 200 mcg	\$1,280.94
4/17/2015	Subsys 1200 mcg	\$15,202.14
5/12/2015	Subsys 1200 mcg	\$15,146.14
6/1/2015	Subsys 1200 mcg	\$20,194.60
6/24/2015	Subsys 1200 mcg	\$20,194.60
7/22/2015	Subsys 1200 mcg	\$23,161.25
8/19/2015	Subsys 1200 mcg	\$23,161.25
9/16/2015	Subsys 1200 mcg	\$23,161.25
10/12/2015	Subsys 1200 mcg	\$23,161.25
11/2/2015	Subsys 1200 mcg	\$23,161.25
12/1/2015	Subsys 1200 mcg	\$23,161.25

116. M.G. did not have a cancer diagnosis. Subsys is not indicated by the patient's diagnoses. Dr. Baddick prescribed Subsys to M.G. without a legitimate medical purpose and outside the usual course of professional practice. Therefore, none of the Subsys prescriptions Dr. Baddick wrote for M.G. were valid, lawful prescriptions under Pennsylvania law.

#### **PATIENT A.P.**

117. At times relevant to this Complaint, Patient A.P. was a TRICARE beneficiary.

118. An Insys sales representative was advised by a mutual acquaintance that A.P. suffered from sarcoidosis.

119. In June of 2015, the Insys sales representative visited A.P. at her home.

120. During the visit to A.P.'s home, the Insys sales representative recommended that A.P. make an appointment with Dr. Baddick to obtain a Subsys prescription.

121. At the time of the Insys sales representative's visit to A.P.'s home, A.P. was not being treated by Dr. Baddick. In fact, at the time of the home visit, A.P. was unfamiliar with Dr. Baddick.

122. A.P.'s first medical appointment with Dr. Baddick was June 10, 2015.

123. On June 10, 2015, Dr. Baddick saw A.P. for the first time. Medical records maintained by Dr. Baddick stated that A.P. would like a prescription for Subsys.

124. An Adult Health History for NEW Patients completed by A.P. on June 10, 2015, stated that the main reason for the visit was chronic pain. The medical history completed by A.P. at the initial visit did not indicate that A.P. was or had been diagnosed with cancer.

125. The medical records indicated that Dr. Baddick diagnosed and/or was treating A.P. for sarcoidosis, endometriosis, Raynaud's phenomenon, and chronic pain syndrome.

126. The medical records indicated that A.P. should discontinue an Oxycodone prescription and that Dr. Baddick would obtain old records [medical records from A.P.'s other health care providers].

127. After the initial appointment, Dr. Baddick prescribed Subsys 200 mcg four times a day (120 units) to A.P. on June 10, 2015. He also prescribed OxyContin 20 mg to A.P.

128. On June 11, 2015, Dr. Baddick signed an INSYS Reimbursement Center and Patient Authorization & Referral Form indicating that A.P. had been diagnosed with cancer, sarcoidosis, chronic pain, chronic pain syndrome, and endometriosis.

129. A.P.'s June 10, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to TRICARE. TRICARE paid the pharmacy \$5,502.13 for the June 10<sup>th</sup> Subsys prescription written by Dr. Baddick.

130. On or about June 22, 2015, Dr. Baddick instructed a medical assistant in his office to prepare a prescription form for 1200 mcg (240 units) for A.P.

131. Dr. Baddick signed a prescription form dated June 22, 2015, prescribing Subsys 1,200 mcg four times a day (240 units) to A.P. Dr. Baddick has not provided any records that indicate that he met with A.P. on or around June 22, 2015.

132. A.P.'s June 22, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to TRICARE. TRICARE paid the pharmacy \$20,798.68 for the June 22<sup>nd</sup> Subsys prescription written by Dr. Baddick.

133. Dr. Baddick's medical records indicate that he saw A.P. on July 8, 2015, for a medication check and prescription refills for OxyContin and Subsys. The medical notes state that A.P. was not due for a Subsys prescription until July 22, 2015. The medical notes also reflect that A.P. was diagnosed with sarcoidosis, chronic pain syndrome, rheumatoid arthritis, and Raynaud's phenomenon.

134. On July 21, 2015, Dr. Baddick prescribed Subsys 600 mcg four times a day (240 units) to A.P.

135. A.P.'s July 21, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to TRICARE. TRICARE paid the pharmacy \$23,857.07 for the July 21<sup>st</sup> Subsys prescription written by Dr. Baddick.

136. Dr. Baddick's medical records indicate that he saw A.P. on August 3, 2015, for a monthly medication check and prescription refills for OxyContin and Subsys. The medical notes again reflect that A.P. was diagnosed with sarcoidosis, chronic pain syndrome, rheumatoid arthritis and Raynaud's phenomenon.

137. On August 3, 2015, Dr. Baddick prescribed Subsys 600 mcg four times a day (120 units) to A.P.

138. A.P.'s August 3, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to TRICARE. TRICARE paid the pharmacy \$11,918.66 for the August 3<sup>rd</sup> Subsys prescription written by Dr. Baddick.

139. Dr. Baddick's medical records indicate that he saw A.P. on August 31, 2015, for a monthly medication check and prescription refills. The notes reflect that A.P. expressed concerns regarding the risks of taking Subsys and had not taken Subsys for two days. The medical notes



again reflect that A.P. was diagnosed with sarcoidosis, chronic pain syndrome, rheumatoid arthritis, and Raynaud's phenomenon.

140. Notwithstanding, A.P.'s concerns, on the same day, August 31, 2015, Dr. Baddick prescribed Subsys 600 mcg four times a day (120 units) to A.P.

141. A.P.'s August 31, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to TRICARE. TRICARE paid the pharmacy \$11,891.66 for the August 31<sup>st</sup> Subsys prescription written by Dr. Baddick.

142. Dr. Baddick's medical records indicate that he saw A.P. on September 28, 2015, for a monthly medication check and prescription refills. The medical notes again reflect that A.P. was diagnosed with sarcoidosis, chronic pain syndrome, rheumatoid arthritis, and Raynaud's phenomenon.

143. On September 28, 2015, Dr. Baddick prescribed Subsys 600 mcg four times a day (120 units) to A.P.

144. A.P.'s September 28, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim

to TRICARE. TRICARE paid the pharmacy \$11,819.66 for the September 28<sup>th</sup> Subsys prescription written by Dr. Baddick.

145. Dr. Baddick's medical records indicate that he saw A.P. on October 27, 2015, for a monthly medication check and prescription refills for OxyContin and Subsys. The medical notes again reflect that A.P. was diagnosed with sarcoidosis, chronic pain syndrome, rheumatoid arthritis, and Raynaud's syndrome.

146. On October 27, 2015, Dr. Baddick prescribed Subsys 600 mcg four times a day (120 units) to A.P.

147. A.P.'s October 27, 2015, Subsys prescription written by Dr. Baddick was filled by a pharmacy and the pharmacy submitted a claim to TRICARE. TRICARE paid the pharmacy \$11,856.13 for the October 27<sup>th</sup> Subsys prescription written by Dr. Baddick.

148. Dr. Baddick's medical records indicate that he saw A.P. on November 25, 2015, a for monthly medication check and prescription refills for OxyContin and Subsys. The medical notes again reflect that A.P. was diagnosed with sarcoidosis, chronic pain syndrome, rheumatoid arthritis, and Raynaud's phenomenon.

149. On November 25, 2015, Dr. Baddick prescribed Subsys 600 mcg four times a day (120 units) to A.P.

150. There is no record of A.P.'s November 25, 2015, Subsys prescription ever being filled.

151. Dr. Baddick's medical records indicate that he saw A.P. for her last medical appointment on December 16, 2015, for a monthly medication check and prescription refills. The medical notes reflect that A.P. informed Dr. Baddick that A.P. was no longer taking Subsys. The medical notes again reflect that A.P. was diagnosed with sarcoidosis, chronic pain syndrome, rheumatoid arthritis, and Raynaud's phenomenon.

152. During the six months Dr. Baddick saw A.P., there is no record that Dr. Baddick ever requested or obtained records from any health care provider that had previously treated or was treating A.P.

153. During the six months Dr. Baddick saw A.P., there is no record that Dr. Baddick ever ordered blood work for A.P.

154. During the six months Dr. Baddick saw A.P., there is no record that Dr. Baddick ever ordered any diagnostic tests for A.P., beyond urine (drug) screens.

155. All of Dr. Baddick's prescriptions for Subsys to Patient A.P. from June of 2015 through October 2015 are identified below

<b>Date of Rx</b>	<b>Details/Dosage</b>	<b>Paid by Tricare</b>
6/10/2015	Subsys 200 mcg	\$5,502.13
6/22/2015	Subsys 1200 mcg	\$20,798.68
7/21/2015	Subsys 600 mcg	\$23,857.07
8/3/2015	Subsys 600 mcg	\$11,918.66
8/31/2015	Subsys 600 mcg	\$11,891.66
9/28/2015	Subsys 600 mcg	\$11,891.66
10/27/2015	Subsys 600 mcg	\$11,856.13

156. A.P. did not have a cancer diagnosis. Subsys is not indicated by A.P.'s diagnoses. Dr. Baddick prescribed Subsys to A.P. without a legitimate medical purpose and outside the usual course of professional practice. Therefore, none of the Subsys prescriptions Dr. Baddick wrote for A.P. were valid, lawful prescriptions under Pennsylvania law.

### **COUNT 1**

#### **False or Fraudulent Claims to Medicare 31 U.S.C. § 3729(a)(1)(A)) (previously 31 U.S.C. § 3729(a)(1)(1986))**

157. The United States repeats and realleges paragraphs 1 through 156 above.

158. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.* as amended.

159. Dr. Baddick knowingly, or with reckless disregard, caused to be

presented false or fraudulent claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A), specifically, Dr. Baddick caused a pharmacy to submit requests for payment to Medicare Part D Plan Sponsors for Subsys prescriptions that were false or fraudulent for two reasons. First, the Subsys prescriptions were not issued for a legitimate medical purpose and therefore not for “medically accepted indications,” and thus not covered Medicare Part D drugs. 42 U.S.C. § 1395w-102(e)(1), referring to § 1395w-102(e)(4), which incorporates the definition of “medically accepted indication” found in § 1396r-8(k)(6). Second, Subsys was dispensed without a valid prescription under Pennsylvania law, 28 Pa. Code § 25.51 and § 25.52, because the prescriptions were not issued for a legitimate medical purpose by Dr. Baddick acting in the usual course of professional practice, and thus not covered Medicare drugs. 42 U.S.C. § 1395w-102(e); 42 C.F.R. § 423.104(h).

160. Because of Dr. Baddick’s acts, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the False Claims Act, as well as a such civil penalties as are permitted by law, for each claim submitted to the Medicare Program.

## COUNT 2

### False Statements to Medicare

#### 31 U.S.C. § 3729(a)(1)(B)(previously 31 U.S.C. § 3729(a)(2)(1986))

161. The United States repeats and realleges paragraphs 1 through 160 above.

162. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.* as amended.

163. Dr. Baddick knowingly caused to be made or used a false record or statement material to a false or fraudulent claim, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B), specifically, Dr. Baddick caused a pharmacy to submit false information to Medicare Part D Plan Sponsors for Subsys prescriptions that were false or fraudulent for two reasons. First, the Subsys prescriptions were not issued for a legitimate medical purpose and therefore not for “medically accepted indications,” and thus not covered Medicare Part D drugs. 42 U.S.C. § 1395w-102(e)(1), referring to § 1395w-102(e)(4), which incorporates the definition of “medically accepted indication” found in § 1396r-8(k)(6). Second, Subsys was dispensed without a valid prescription under Pennsylvania law, 28 Pa. Code § 25.51 and § 25.52 because the prescriptions were not issued for a legitimate medical purpose by Dr.

Baddick acting in the usual course of professional practice, and thus not covered Medicare drugs. 42 U.S.C. § 1395w-102(e); 42 C.F.R. § 423.104(h).

164. Because of Dr. Baddick's acts, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the False Claims Act, as well as a such civil penalties as are permitted by law, for each claim submitted to the Medicare Program.

### **COUNT 3**

#### **False or Fraudulent Claims to TRICARE 31 U.S.C. § 3729(a)(1)(A) (previously 31 U.S.C. § 3729(a)(1)(1986))**

165. The United States repeats and realleges paragraphs 1 through 164 above.

166. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.* as amended.

167. Dr. Baddick knowingly caused to be presented false or fraudulent claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A), specifically, Dr. Baddick caused a pharmacy to submit requests for payment to TRICARE for Subsys prescriptions that were false or fraudulent for two reasons. First, the

prescriptions were not issued for a legitimate medical purpose and therefore not “medically necessary prescription drugs required in the treatment of an illness or injury,” and thus not covered by TRICARE. 32 C.F.R. § 199.4. Second, Subsys was dispensed without a valid prescription under Pennsylvania law, 28 Pa. Code § 25.51 and § 25.52, because the prescriptions were not issued for a legitimate purpose by Dr. Baddick acting in the usual course of professional practice, and thus not covered TRICARE drugs.

168. Because of Dr. Baddick’s acts, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the False Claims Act, as well as a such civil penalties as are permitted by law, for each claim submitted to TRICARE.

#### **COUNT 4**

##### **False Statements to TRICARE 31 U.S.C. § 3729(a)(1)(B) (previously 31 U.S.C. § 3729(a)(2)(1986))**

169. The United States repeats and realleges paragraphs 1 through 168 above.

170. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.* as amended.

171. Dr. Baddick knowingly caused to be made or used a false



record or statement material to a false or fraudulent claim, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B), including Dr. Baddick caused a pharmacy to submit false information to TRICARE for medications, including controlled substances, that were false or fraudulent for two reasons. First, the prescriptions were not issued for a legitimate medical purpose and therefore not “medically necessary prescription drugs required in the treatment of an illness or injury,” and thus not covered by TRICARE. 32 C.F.R. § 199.4. Second, Subys was dispensed without a valid prescription under Pennsylvania law, 28 Pa. Code § 25.51 and § 25.52, because the prescriptions were not issued for a legitimate purpose by Dr. Baddick acting in the usual course of professional practice, and thus not covered TRICARE drugs.

172. Because of Dr. Baddick’s acts, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the False Claims Act, as well as a such civil penalties as are permitted by law, for each claim submitted to TRICARE.

## **COUNT 5**

### **Payment by Mistake of Fact**

173. The United States repeats and realleges paragraphs 1

through 172 above.

174. Dr. Baddick caused the submission of (a) pharmacy's requests for payment to Medicare Part D Plan Sponsors for Subsys that were not dispensed for a legitimate medical purpose under the CSA and/or that lacked a valid prescription under Pennsylvania law as required by Medicare and the CSA, (b) a pharmacy's requests for payment to TRICARE for Subys prescriptions that were not dispensed for a legitimate medical purpose under the CSA and/or that lacked a valid prescription under Pennsylvania law as required by TRICARE and the CSA and such claims represent misrepresentations of material facts in that Dr. Baddick caused misrepresentations that the medications and services were reimbursable as billed.

175. The United States paid more money to the pharmacy than it would have based on the erroneous belief that the pharmacy was entitled to reimbursement and without knowing that Dr. Baddick caused to be submitted, the pharmacy's requests for payment for Subsys prescriptions that were not covered to Medicare Part D Plan Sponsors and to TRICARE.

176. The United States, acting in reasonable reliance that the

pharmacy's claims and/or the related PDE data or pharmacy's TRICARE claims were accurate, complete, and truthful, paid Medicare Part D Plan Sponsors and/or the pharmacy certain sums of money to which they were not entitled, and Dr. Baddick is thus liable to account and pay to the United States, which are to be determined at trial.

### **PRAYER FOR RELIEF**

Wherefore, the United States demands and prays that judgment be entered in its favor and against Dr. Baddick as follows:

A. On Counts 1, 2, 3, and 4 for the amount of the United States' damages, trebled as required by law, and such penalties as are permitted by law, together with all such further relief as may be just and proper.

B. On Count 5 for payment by mistake, for the amounts he caused Medicare and TRICARE to pay to a pharmacy to which the pharmacy was not entitled, plus interest, costs, and expenses.

C. All other relief as may be required or authorized by law in the interests of justice.

## DEMAND FOR JURY TRIAL

The United States demands a jury trial.

Respectfully,

JOHN C. GURGANUS  
UNITED STATES ATTORNEY

*s/D. Brian Simpson*

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